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EXAMINER GEORGE, PATRICIA ANN				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/542,200

Applicant(s)

ITO ET AL.

Examiner

PATRICIA A. GEORGE

Art Unit

1789

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/11 has been entered.

Affidavit

The affidavit, of 1/28/2011 has been considered, and reviewed, also the affidavit, of 9/27/2010 has been reconsidered. The office appreciates the time and experience of Noboru Sakaguehi, co-inventor of this patent application.

In the affidavit of 1/28/2011, Mr. Sakaguehi asserts that: 1) the experimental data in Declaration of September 27, 2010, is commensurate, with the scope of the claims because 2) experimental data provided, such as the analysis of Enriched Rice Nos. 1-4, of 9/27/2010, makes statistically clear that the novelty of the invention lie within differences in terms of residual ratio (%) and loss percentage (%) which is 3) due to only one factor: the enzymatically decomposed lecithin, and the other ingredients do not affect the experimental results as explained below.

In response, the arguments that: 1) the experimental data in Declaration of September 27, 2010, is commensurate, with the scope of the claims because: 3) due to

only one factor: the enzymatically decomposed lecithin, and the other ingredients do not affect the experimental results as explained below does not appear to take the scope of the claims into consideration.

On the matter of:

1) and 3) Applicant makes correlation between the structure of the rice and the function of the enzymatically decomposed lecithin, however when looking at the claim construction, one skilled in the art would not be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the claims themselves provide no disclosure of function and minimal structure when applicant insists there is a well-established correlation between structure and function, therefore there appears to be a disconnect between what the applicant describes as the structure of the product and the novelty of the claimed invention: the effect or function of the enzymatically decomposed lecithin.

Claim construction is an essential part of the examination process, and in this case, based on the remarks in the affidavit, and the remark provided by applicant's representative, submitted at the same time, the three independent claims do not appear to disclose best mode contemplated by the inventor: and appear to be failing to set forth the subject matter which applicant(s) regard as their invention.

Claim 1 recites a product by process wherein rice or barley is coated twice, 1) with an emulsifying agent composition, and 2) further with oil and a fatty acid ester mixture; the emulsifying agent is clearly limited as an enzymatically decomposed

lecithin; however no relationship is established in the claims between structure and function, as asserted.

Claim 2 recites a product by process wherein rice or barley is coated once, with a mixture comprising an 1) iron salt, a hydrogenated oil and a polyglycerol fatty acid ester, with no claim to an enzymatically decomposed lecithin and no relationship is established between structure and function, as asserted.

Claim 3 recites a product by process wherein rice or barley is coated with a 1) mixture comprising an emulsifying agent-coated iron salt composition, vitamins, a hydrogenated oil and a polyglycerol fatty acid ester, wherein the emulsifying agent is an enzymatically decomposed lecithin, however no relationship is established in the claims between structure and function, as asserted.

Emphasis within all of the claims appears to be toward products, coated rice and barley compositions, are process with a varied set of components, including 1 or 2 coatings, however despite applicant assertions which illustrate there is a well-established correlation between the structure of the coated product and the function of the enzymatically decomposed lecithin, the claims themselves do not appear to represent such an assertions, and therefore applicant's arguments are not commensurate with the claimed language.

On the matter of 2) statistical evidence:

The "Detailed Procedures for Preparing the Enriched Rice", of the declaration of 9/27/10, appears to provide only one example wherein the enzymatically decomposed

lecithin was applied to rice.

1) Enriched Rice 4, which reported about 5% to 15% higher residual ratios of the four items tested after the treatment of the rice.

Looking to applicant's own specification (AOS), it appears that four examples are discussed toward the use of the use of the enzymatically decomposed lecithin:

2) Example 1: Mixtures I, J, K, and L of, Tables 1 & 2 illustrate, ranges of about 50 to 100 % loss of the vitamins and minerals tested, in comparison to the mixture that did not receive the enzymatically decomposed lecithin: Mixtures M, N, and O.

3) Example 2: Toward composition B, corresponding data not found in results tables.

4) Example 14: Toward mixture S, corresponding data not found in results tables.

5) Example: 15: Toward mixture T, corresponding data not found in results tables.

In summary, it appear that applicant has provided 5 example, from all sources, which yield a total of 5 data points to review, and three of which do not appear to have correlated data for the results of the experiment, and therefore, the population of data of those examples does not appear to be complete (e. g. missing data points); and further, the remaining five data points, comprise such a limited group of numbers to review,

there is not enough data provided to make a statistical comparison to determine unexpected results.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, and all claims dependent on them, are rejected under 35

U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon assertions presented by applicant who places emphasis on the novelty of the invention being only based on the correlation between the structure of the rice and the function of the enzymatically decomposed lecithin. Independent claims 1-3 comprise a product by process of use of individual components, with no disclosure of said function, and the scope of the claims do not appear to contain the vital subject matter, asserted in affidavits, remarks, and office interviews, in such a way that comply said function.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and all claims dependent on them are rejected under 35

U.S.C. 112, second paragraph, as failing to set forth the subject matter which

applicant(s) regard as their invention. Evidence that independent claims 1-3 fail to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed 1/28/11 and 2/25/11. In those papers, applicant has stated "any difference in terms of residual ratio (%) and loss percentage (%) is due to just one factor - - the enzymatically decomposed lecithin. The other ingredients ...do not affect the experimental results".

Therefore, this statement indicates that the invention is different from what is defined in the claim(s) because it illustrates a strong correlation between the structure of the rice and the function of the enzymatically decomposed lecithin, however, when looking at the claim construction, one skilled in the art would not be able to predict with a reasonable degree of confidence the novel structure of the claimed invention is from a recitation of sole function with the enzymatically decomposed lecithin. Thus, the claims themselves provide no disclosure of function and minimal structure when applicant insists there is a well-established correlation between structure and function, and therefore there appears to be a failing to set forth the subject matter which applicant(s) regard as their invention, because there is a disconnect between what applicant describes as the structure of the product and the novelty of the claimed invention: the effect or function of the enzymatically decomposed lecithin. Further, independent claim 2 does not appear to even claim the stated " one factor - - the enzymatically decomposed lecithin".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9-11, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misaki in view of the combination of Kwak, Nanbu, and Tamaki (6,436,462).

The reference of WO/2008/140065 is provided as evidence.

Misaki teaches grain compositions, such as rice or barley (column 1, lines. 7-8) are coated with vitamins (column 2, lines. 43-45) and an iron salt (column 9, line 47) that have further been coated with an emulsifying agent (column 9, line 49).

Misaki also teaches vitamin and mineral enriched rice that has been coated (column 1, lines 54-57) with hydrogenated oil (column 2, lines 56-57) and glycerol fatty acid esters (column 2, line 65).

Misaki teaches rice or barley (column 1, lines 7-8) coated with an iron salt (column 9, line 47), hydrogenated oil (, column 2, lines 56-57) and glycerol fatty acid esters (column 2, line 65), as in claim 2.

Misaki does not teach the coating of the iron salt with an emulsifying agent.

Kwak teaches methods of improving the solubility of minerals, such as iron, by encapsulating (i.e. coating) the minerals used in food, so that more of the mineral is

usable by the consumer. Kwak further teaches that conventionally the iron has been added to food as a means to increase iron content, however problems arise because of low solubility of the mineral, and therefore means to alleviate this problem are to try to microencapsulate the iron with a water soluble polyglycerin monostearate which is an emulsifying agent and equivalent to a polyglycerol fatty acid ester (col. 3, lines 21-22), as in claims 1 and 3. Therefore Kwak teaches an emulsifier- coated iron salt composition, similar to that claimed, as for use in foods. See reference starting at Background, and then col. 3, lines 15-20.

In regard to particle size, Kwak teaches that problems in achieving the proper sizes are known because larger particle sizes are easily precipitated, thus causing the value of the commodity to be lowered, and being distasteful to consumers.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of making a food product which provides vitamins and minerals to the consumer, including the provision of iron salt, as Misaki, to include coating of the iron salt with an emulsifying agent, as claimed, because Kwak teaches that such a limitation is known to overcome problems in the art and provides benefits such as improving solubility of iron and providing encapsulation so that more of the mineral is usable by the consumer.

The combined teaching of Misaki and Kwak fails to teach the specifically claimed particle size for the emulsified coated iron salt.

Nanbu, teaches that similar iron salts used for foods, having similar emulsified coated components such as polyglycerol fatty acid esters with oils, are effective for enriching food and feeds because they supplement individuals with deficiencies and maintain the good flavor of the food or feed; that they are produced to have particles sizes of less than 0.5 microns, as claimed; and that the absorption of mineral nutrients which typically have low absorptivity when taken intracorporeally will be improved. See the Background and starting at figure 3 and col. 4, lines 14+, including col. 5, lines 45+.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of making a food product which provides vitamins and minerals to the consumer, including the emulsified coated iron salt, as Misaki, to include coated iron salts in a particulate range of less than 0.5 microns, as provided by Nanbu, because the modified teaching of Misaki illustrates in Kwak that the trend in the art is to overcome the use of large particles sizes which create problems such as low solubility, bad taste, and a poor delivery of the desired dose to the consumer; and because Nanbu teaches the use of emulsified coated iron salts having particles sizes of less than 0.5 microns allow for an improvement in the absorption of mineral nutrients.

Although, the modified teaching of Misaki in view of Kwak and Nanbu, teaches the use of emulsifying polyglycerol fatty acid esters as a coating agent for iron salt to make them more soluble so that a larger quantity of usable mineral is deliver to the

consumer, the teaching fails to provide applicant's specifically claimed emulsifying agent, an enzymatically decomposed lecithin.

Tamaki teaches methods of making rice compositions that include iron salts, further include the emulsifiers, such as sucrose fatty acid esters, polyglycerol fatty acid esters, organic acid monoglycerides, lysolecithin, and diglycerol fatty acid esters, as effective additives.

The reference of WO/2008/140065 is provided as evidence that enzymatically decomposed lecithin is also referred to as lysolecithin, and that lysolecithin inherently provide improved hydrophilicity. See reference starting at para. 0060.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of making a rice or barley grain product which provides vitamins and minerals to the consumer, including the emulsified coated iron salt, as Misaki, to include the specifically claimed enzymatically decomposed lecithin (i.e. lysolecithin), because one of skill would have a reasonable expectation of success in the teaching of Tamaki which illustrates that enzymatically decomposed lecithins are simple substitutions for the emulsifying polyglycerol fatty acid esters taught by the modified teaching of Tamaki, and further that they are suitable for the intended use of emulsifying rice compositions. Furthermore enzymatically decomposed lecithins (i.e. lysolecithin) inherently provides the benefit of improved hydrophilicity (i.e. water solubility), a property which is known to be beneficial in coating for rice and barley grain compositions.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention, because they work together to overcome the well known problems in the art by providing benefits to food compositions known to deliver vitamins and minerals to the consumer.

The prior art included each element claimed although not necessarily in a single reference, and one of ordinary skill in the art could have combined the elements as claimed by known methods of forming mineral and vitamin enriched grains, and in combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable. Further, a predictable use of prior art elements according to their established functions to achieve a predictable result is *prima facie* obvious. Further, *KSR Int'l Inc. v. Teleflex Inc.*, 127 S Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) teaches that "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton," and that "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."

In summary, the modified teaching above provides benefits for modifying the primary reference to include known components to the claims composition, and therefore the instant invention does not appear to be novel or exceed the inferences

and creative steps that a person of ordinary skill in the art would employ, based on known teachings of the art.

As for claims 9-11, the modified teaching of Misaki, teaches:

Nanbu teaches the use of: ferric pyrophosphate, iron lactate, ferric chloride, and ferrous sulfate. See Nanbu reference starting at Fig. 2, col.5, line 55+, col. 7 lines 64+, and Example 1; and

Kwak teaches the use of: ferric pyrophosphate, and ferric citrate. See Kwak reference starting at "Mixing Coating Agent With Iron".

As for claims 15-16, Misaki teaches nutrients for rice include vitamin A, vitamin C, vitamin D, vitamin E, nicotinic acid, and panthothenic acid. See reference starting at col. 2, l. 40.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misaki in view of the combination of Kwak, Nanbu, and Tamaki, as cited in the rejections of claims 1-3, 9-11, and 15-16, above, further in view of Kajishima (JP2003-076699).

As for claims 12-14, although the teaching of Misaki provides for the use of fatty acid esters, the reference does not provide the specifically claimed polyglycerol fatty acid ester, an ester formed between a polyglycerol having an average degree of polymerization of 3 to 11 and a fatty acid having 6 to 22 carbon atoms.

The reference of Kajishima teaches rice products are made by using a process which includes lecithin and fatty acid esters, including: hexaglycerin (e.g. synonyms include hexaglycerol, polyglycerin 06, PB60))condensation ricinoleic acid ester , a polyglycerol condensed ricinoleate (See reference starting at abstract), which appears to read on a polyglycerol fatty acid ester, an ester formed between a polyglycerol having an average degree of polymerization of 3 to 11 and a fatty acid having 6 to 22 carbon atoms, because when looking to applicant's own specification (p. 0029+) on clarification of types of esters which meet the claimed requirement, it is noted that the preferable polyglycerol fatty acid ester include pentaglycerol condensed ricinoleate.

Kajishima teaches the use of lecithin and fatty acid esters for rice compositions provides benefits such as improving the peeling properties from a cooking pot and loosening properties of the rice grains from each other after cooked to provide better utilization of the rice. See reference starting at abstract.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the method of making a rice composition, as Misaki, to include an ester formed between a polyglycerol having an average degree of polymerization of 3 to 11 and a fatty acid having 6 to 22 carbon atom, as claimed, because the reference of Kajishima teaches such an hexaglycerin condensation ricinoleic acid ester is suitable for the intended use of rice compositions, and in combination with lecithin provides benefits such as improving the peeling properties from a cooking pot and loosening properties of the rice grains from each other after cooked to provide better utilization of the rice.

Response to Arguments

It is asserted, that the Amendment and Rule 132 Declaration filed on January 28, 2011 sufficiently address this rejection.

In response, please note the Affidavit section above, which responds to the Amendment and Rule 132 Declaration filed on January 28, 2011, including its referencing to the affidavit, of 9/27/2010.

It is asserted that the Amendment of September 27, 2010, the Rule 132 Declaration establishes unexpected results for the present invention, because Tables I-III, the Rule 132 Declaration of record shows better retention of vitamins and minerals after washing, after cooking, and during long term storage of the non- cooked product.

Please note the response on the subject matter of unexpected results for the present invention in the Affidavit section above, which points to 1) applicant's placement of a strong correlation between the structure of the rice and the function of the enzymatically decomposed lecithin, however when looking at the claim construction, one skilled in the art would not be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function, and therefore the scope of the claim does not appear to encompass the asserted novel feature of the invention, and the experiments toward the asserted scope are not commensurate with the claims; and it appear that applicant has provided 5 examples, from all sources, which is not enough data to make a statistical comparison to determine unexpected results.

Applicant's representation, further assert that any differences between examples can be attributed to the claimed emulsifying agent-coated iron salt composition having the enzymatically decomposed lecithin, which implies there is a correlation between the structure of the rice and the function of the enzymatically decomposed lecithin.

In response, this assertion presents an admission that novelty lie within the correlation between the structure of the rice and the function of the enzymatically decomposed lecithin. The claims do not appear to be crafted in a manner which claims this distinct and novel feature of the invention, and therefore such arguments and experiments toward its conclusion are not commensurate in scope of the claims. Further, one of the three independent claims makes no mention of the composition even comprising emulsifying agent-coated iron salt composition having the enzymatically decomposed lecithin.

It is asserted that, the Examiner has required testing of other embodiments.

In response, in regard to experimentation of record, and the claims as submitted, draft, there appears to be discrepancies between the scope of the claims, and what is being asserted by applicant and their representative on what the novel feature of the claim are. Burdensome and enormous amount of testing is not being required, only a correlation between what is claimed and the experimental data, or a correlation between the data and the claims.

It is asserted that properties/results such as a lower percent of loss of vitamins after washing do not have to be claimed.

In response, the examiner agrees, however since applicant and their representative continue to assert that novelty lie within the correlation between the structure of the rice and the function of the enzymatically decomposed lecithin, it appears that the claims do not represent the novel feature of the invention.

It is asserted that evidence of unexpected results have been shown, are sufficient, and allowability is requested.

In response, this argument is not persuasive, for at least the following reasons:

1) Applicant's statement that differences in terms of residual ratio (%) and loss percentage (%) is due to only one factor: the enzymatically decomposed lecithin and the other ingredients do not affect the experimental results as explained below;

2) The prior art:

A) The reference of WO/2008/140065 providing evidence that enzymatically decomposed lecithin is also referred to as lysolecithin, and that lysolecithin inherently provide improved hydrophilicity. See reference starting at para. 0060;

B) Tamaki teaches methods of making rice compositions that include lysolecithin (lecithin);

3) Claims 1-3, and all claims dependent on them, are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed;

4) Claims 1-3, and all claims dependent on them are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention; and

5) The submission by applicant does not provide evidence of unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA A. GEORGE whose telephone number is (571) 272-5955. The examiner can normally be reached on Tues. - Thurs. between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Humera Sheikh can be reached on (571)272-0604. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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